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| APPLICATION NO.                        | FILING DATE             | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------------------|------------------------|---------------------|------------------|
| 10/648,650                             | 08/25/2003              | Marcus Andrew Stoodley | 11280.1002cip       | 3875             |
| PELOQUIN , F                           | 7590 01/03/2007<br>PLLC |                        | EXAM                | IINER            |
| MARK PELOQUIN                          |                         |                        | COBY, FRANTZ        |                  |
| 800 FIFTH AV<br>SUITE 4100             | Æ .                     |                        | ART UNIT            | PAPER NUMBER     |
| SEATTLE, WA 98104-3100                 |                         |                        | 2161                |                  |
|  | ·                       |                        |                     |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE |                         | MAIL DATE              | DELIVERY MODE       |                  |
| 3 MONTHS                               |                         | 01/03/2007             | PAPER               |                  |

## Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|  |  | Application No.   | Applicant(s)    |  |  |  |
|--|--|---|-----------------|--|--|--|
| Office Action Summary  |  | 10/648,650  | STOODLEY ET AL. |  |  |  |
|  |  | Examiner  | Art Unit        |  |  |  |
|  |  | Frantz Coby   | 2161            |  |  |  |
| Period fo  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply                          |   |                 |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |   |                 |  |  |  |
| Status   |  |   |                 |  |  |  |
| 1)⊠  | Responsive to communication(s) filed on <u>02 Oc</u>   | otober 2006   |                 |  |  |  |
|  |  | action is non-final.  | •               |  |  |  |
| 3)   |  |   |                 |  |  |  |
| -,   | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |   |                 |  |  |  |
|  |  | parto quayro, todo oto, tt  | 100 0.0. 210.   |  |  |  |
| Dispositi  | on of Claims   |   |                 |  |  |  |
| 4)⊠  | Claim(s) $\underline{\text{1-39}}$ is/are pending in the application.  |   |                 |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |                 |  |  |  |
| 5)   | Claim(s) is/are allowed.   |   |                 |  |  |  |
| 6)⊠  | Claim(s) <u>1-39</u> is/are rejected.  |   |                 |  |  |  |
| 7)   | Claim(s) is/are objected to.   |   |                 |  |  |  |
| 8)[  | Claim(s) are subject to restriction and/or   | election requirement.   |                 |  |  |  |
| Applicati  | on Papers  |   |                 |  |  |  |
| 9)   | The specification is objected to by the Examiner   | :   |                 |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.  |  |   |                 |  |  |  |
| •  | Applicant may not request that any objection to the d  |   |                 |  |  |  |
|  | Replacement drawing sheet(s) including the correction  |   | ` '             |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |   |                 |  |  |  |
| Priority under 35 U.S.C. § 119   |  |   |                 |  |  |  |
| 12)  |  |   |                 |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |   |                 |  |  |  |
| 2) 🔲 Notice<br>3) 🔲 Inforn   | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date | 4) Interview Summa<br>Paper No(s)/Mail<br>5) Notice of Informa<br>6) Other: | Date            |  |  |  |

This is in response to Applicant's amendment filed on October 02, 2006 in which claims

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1-39 are presented for examination.

Status of Claims

Claims 1-39 are pending, of which, claims 1, 13, 22, 30 and 36 are in independent form.

Response to Arguments

Applicant's arguments filed on the aforementioned date have been fully considered but they are not persuasive. Therefore, the rejection of claims 12 under section 112 2<sup>nd</sup> paragraph and claims 1-39 under sections 102 and 103 mailed on March 31, 2006 remains.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 recites the limitation "the hierarchical tree" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3, 4, 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Barry et al (Barry), US 5,991,729, 23 November 1999.

Barry is directed to generating patient-specific medical reports that include diagnostic analysis, which corresponds to analyzing healthcare data [COL 1 lines 5-18].

### As to claim 1:

The claim as a whole is taught essentially as claimed in Barry at COL 2 line 66 to COL 3 line 62. In more particular: Barry uses a relational database to maintain data sets specific to a particular patient [FIG 1; COL 1 lines 10-13]. A patient identifier is used [COL 2 line 67]. It is inherent in a relational database system that data is maintained in tables, organized by criteria (column designators). [See also COL 1 line 67 to COL 2 line 3]. Barry manages data in the categories of diagnosis [COL 2 lines 32-34] and

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outcomes in the form of reports [COL 2 lines 49-59], treatment COL 3 lines 13-18], all of which are identified by patient.

Archival information concerning groups common to a diagnosis at least is determined in order to display a report (which corresponds to a presentation). See, for instance, the example of Barrett's Esophagus [COL 4 lines 27-52].

As to claim 3, the Barrett's Esophagus example of Col 4 lines 26-52 is a diagnosis category of pathological examination results.

As to claim 4, Barry sets forth treatment categories for this disease in the passage cited.

As to claim 6, Barry includes multimedia data in the database and reports [COL 4 lines 21-26].

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 5, 7-12 and 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al (Barry), US 5,991,729, 23 November 1999.

As to claim 2, Barry teaches the use of codes such as diagnostic codes, physician codes, and the like, the latter of which is explicitly alphanumeric [COL 2 lines 43-48]. Barry does not address the use of more than one language, but it was well known in the art at the time of the invention for Physicians to use Latin terms in healthcare descriptions. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide for Latin as well as a native language because it supports standard and precise descriptions.

As to claim 5, Barry does not explicitly list the scores and effects as cited, but it would have been obvious to one of ordinary skill in the art at the time of the invention to provide for them because they are useful components of extended treatments and of diagnostic data. Including the elements of claims 7-9 into the system of Barry would have been obvious to one of ordinary skill in the art for similar reasons. They fall within

the category of in tended applications of the invention to specific data that would have been useful as support for the diagnosis reporting of Barry. Using claim 8 as exemplary, treatment regimes are tasks of patient management, the archival information relating to an example such as Barrett's is useful for training of healthcare professionals and/or certification of those tested for diagnostic abilities, and so on. Multimedia files have been addressed above.

As to claims 11 and 12, it was well known in the art at the time of the invention to arrange data in a hierarchical tree for purposes of searching such a manner that lower levels are of increasing specificity. The motivation for such an arrangement is the efficiency of a directed search. T

The elements of claims 30-39 are rejected in the analysis above and these claims are rejected on that basis.

Claims 13-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al (Barry), US 5,991,729, 23 November 1999 in view of Schneiderman, US 5,099,424, 24 March 1992.

As per claims 13-39, Barry does not address the use of a linking event identifier, although clearly any data dealing with a specific patient must identify that patient, no matter what category or table contains the data. Thus Barry must have some

mechanism that provides the same functionality. Barry also does not address patient management explicitly.

Schneiderman is directed to processing clinical data processing that tracks outpatient practice COL 1 lines 9-59]. This is an improvement on prior art that used a patient identifier stored in data records [FIG 26 for example], which in turn include management and surgery records [COL 7 lines 31-39]. The events in Schneiderman include EKG and CXR records [COL 1 line 60 and after].

It would have been obvious to one of ordinary skill to use the linking mechanism of Schneiderman and his prior art in the patient specific medical reports of Barry because they link together data that is both specific to a patient and significant to diagnosis, treatment, and outcome. The combination teaches the use of linked records of the types set forth in both teachings, wherein a linking event identifier can be the patient ID. With this combination, the elements of the claims are rejected in the analysis above and these claims are rejected on that basis.

#### Remarks

The Applicant stated that in response to the nonstatutory obviousness double patenting, a terminal disclaimer is timely file. However, the Examiner respectfully submits that a terminal disclaimer was not filed, nor was entered in the present application. Therefore, claims 1-39 are, again, rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 6,611,846 as detailed above.

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The Applicant also argued, "the Barry reference does not teach each element of Applicant's claim 1". However, the Examiner disagrees with the preceding argument because as detailed, in the rejection, above Barry teaches all the limitations of claim 1.

The Applicant further argued that, "Barry does not provide a method of extracting data pertaining to a plurality of patient which have common criterion". And refer to the claimed language of "determining patient data results for all data sets in a group common to the criterion". However, the Examiner disagrees with the preceding argument because the Applicant argument of extracting data pertaining to a plurality of patient which have common criterion implies that the patients have common criteria; whereas, the claimed language of "all data sets in a group common to the criterion" implies that the data sets have common criterion. Therefore, Barry's searching from which a report can be generated based on an analysis of a biological sample for a patient falls in the category of data sets in a group common to the criterion; namely, the biological sample which implies that the data sets have common criterion.

Furthermore, the Applicant argued, Barry does not teach a database that contains categories of data having subcategories. The Examiner respectfully submits that Barry achieves the aforementioned claimed feature because Barry manages data in the categories of diagnosis [COL 2 lines 32-34] and outcomes in the form of reports [COL 2 lines 49-59], treatment COL 3 lines 13-18], all of which are identified by patient.

Regarding to the Applicant's argument that "a "symbolic code" is not equivalent to the Latin language nor is a "symbolic code" cast in any particular language, it is just that, a "symbolic code" that is language independent. The Office's proffered use of Latin in conjunction with a native language is not equivalent to Applicant's symbolic code", it is not clear whether the applicant is arguing that the "symbolic code" claimed is language independent or not. As to the argument that "the use of Latin in conjunction with a native language is not equivalent to Applicant's symbolic code", the Examiner respectfully submits that the use of Latin in standard and precise description is well known. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide for Latin as well as a native language because it supports standard and precise descriptions.

The Applicant stated that "none of the art cited performs Applicants method process of: "storing a linking event identifier for linking event data to link at least some of the patient data related to a patient management cycle"; "linking patient data of a data set from the categories for a patient management cycle". However, the Examiner disagrees with the aforementioned argument because Schneiderman is directed to processing clinical data processing that tracks outpatient practice COL 1 lines 9-59]. This is an improvement on prior art that used a patient identifier stored in data records [FIG 26 for example], which in turn include management and surgery records [COL 7 lines 31-39]. The events in Schneiderman include EKG and CXR records [COL 1 line 60 and after]. Therefore, it would have been obvious to one of ordinary skill to use the

linking mechanism of Schneiderman and his prior art in the patient specific medical reports of Barry because they link together data that is both specific to a patient and significant to diagnosis, treatment, and outcome. The combination teaches the use of linked records of the types set forth in both teachings, wherein a linking event identifier can be the patient ID. With this combination, the elements of the claims are rejected in the analysis above and these claims are rejected on that basis.

### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1:136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frantz Coby whose telephone number is 571 272 4017. The examiner can normally be reached on Monday-Friday 9:00AM-5: 30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Gaffin can be reached on 571 272 4146. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

December 19, 2006

FRANTZ COBY
PRIMARY EXAMINER